

**IN THE UNITED STATE DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION**

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U.S. DISTRICT COURT
N.D. OF ALABAMA

**CENTRAL ADMIXTURE
PHARMACY SERVICES, INC.,**

Plaintiff,

v.

**ADVANCED CARDIAC
SOLUTIONS, P.C.; CHARLES WALL**

Defendants.

**CIVIL ACTION NO:
CV-00-B-2430-S**

ANSWER AND COUNTERCLAIM

COME NOW Advanced Cardiac Solutions, P.C. ("ACS") and Charles Wall, defendants in the above-referenced case, by and through their undersigned counsel of record, and respond to the plaintiff's Complaint as follows:

ANSWER

1. Defendants are without information or belief to admit or deny the allegations of paragraph 1 of the Complaint, and therefore deny the same.
2. Admitted.
3. Admitted.
4. Defendants admit that Charles Wall is the President of ACS. Defendants deny each and every other allegation of paragraph 4 of the Complaint.
5. Admitted.

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6. Defendants admit that they reside within the Southern Division of the Northern District of Alabama. Defendants deny each and every other allegation of paragraph 6 of the Complaint.

7. Defendants are without information or belief to admit or deny the allegations of paragraph 7, and therefore deny the same.

8. Admitted.

9. Defendants admit that the United States Patent and Trademark Office issued U.S. Patent #4,988,515, entitled "Cardioplegic Solution," and that a copy of this patent is attached to the Complaint. Defendants are without information or belief to admit or deny the remaining averments of paragraph 9 of the Complaint, and therefore deny the same.

10. Admitted.

11. Defendants admit that they ceased selling certain cardioplegic solutions in compliance with the parties' agreement in settlement of previous litigation, and that they have now resumed the sale of these solutions since the terms of that agreement have now expired. Defendants deny each and every other allegation of paragraph 11 of the Complaint.

12. Defendants incorporate by reference their responses to paragraphs 1-11 of the Complaint as set forth above.

13-17. Denied.

WHEREFORE, plaintiff is not entitled to any of the relief requested.

AFFIRMATIVE DEFENSES

1. Plaintiff's claims are barred by the Statute of Limitations.
2. Plaintiff is not entitled to declaratory or injunctive relief on the merits.

3. Plaintiff's Complaint fails to state a claim upon which relief can be granted.
4. Plaintiff has failed to join indispensable parties.
5. Plaintiff's claims are barred by the doctrines of waiver, estoppel, accord and satisfaction, ratification, consent, settlement and release, acquiescence, laches, and unclean hands.
6. The claims of plaintiff's patents are not infringed by any product manufactured, used or sold by defendants.
7. Each of the claims of plaintiff's patent are invalid as a matter of law under Title 35 of the United States Code in accordance with one or more of the following code sections: § 102, § 103, and § 112.
8. Each claim of plaintiff's patent is invalid under 35 U.S.C. § 102 as being anticipated by solutions publically and commonly known, sold, or used in the art prior to the invention of the subject matter of the plaintiff's patent by the patentee.
9. Each claim of the plaintiff's patent is invalid under 35 U.S.C. § 103 as being obvious over the prior art in existence when the invention was allegedly made by the patentee.
10. Each claim of plaintiff's patent is invalid for failure to comply with 35 U.S.C. § 112.
11. Each claim of the plaintiff's patent is void and unenforceable by virtue of the failure of patentee to advise the Patent Office of prior art which was material to the examination of the application.
12. The construction of the claims of plaintiff's patent advanced by the plaintiff are barred by prosecution history estoppel.
13. The plaintiff does not have standing to enforce the terms of the patent.
14. The plaintiff has failed to join the patent owner as an indispensable party.

15. The plaintiff is not entitled to any relief or recovery as it has come into this Court with unclean hands by seeking to enforce a patent which it knows to be invalid, void, unenforceable and not infringed.

16. Defendant's manufacture, use or sale of its accused products do not violate any rights the plaintiff may have under the patent laws of the United States.

17. Plaintiff's claims are barred by its failure to mitigate damages.

18. Plaintiff's claims are barred or diminished by Defendants' right to setoff and/or recoupment.

WHEREFORE, the defendants respectfully request the Court to dismiss each and every claim of the plaintiff's complaint and to deny all the relief requested by the plaintiff.

COUNTERCLAIMS

The defendants claim against the plaintiff as follows:

1. This is an action brought pursuant to the Declaratory Judgement Act, 28 U.S.C. § 2201, *et seq.*, the Lanham Act, 15 U.S.C. § 1051, *et seq.*, and the Patent Laws of the United States. This Court has subject matter jurisdiction over these claims based upon 28 U.S.C. §§ 1331, 1338, and 1367.

2. The plaintiff Central Admixture Pharmacy Services, Inc. ("CAPS") has alleged that it is the exclusive licensee of United States Patent # 4,988,515 (the '515 Patent).

3. The plaintiff has sued the defendants for alleging infringement of that patent.

4. The defendants have not infringed and are not now infringing the '515 Patent.

5. The '515 Patent is invalid for failure to satisfy the conditions for patentability specified in Title 35 of the United States Code, including §§ 102, 103 and § 112 thereof.

6. The claims of the '515 Patent extend to a cardioplegic solution for use in stopping the heart and reducing its energy demands during cardiac surgery, and more specifically to a cardioplegic solution enhanced with certain amino acids. However, the '515 Patent's claims encompass only a limited range of osmolarities, calcium concentrations, and metabolizable substrate concentrations.

7. The use of amino acid enriched cardioplegic solutions, as well as the use of cardioplegic solutions with a variety of osmolarities, calcium concentrations, and metabolizable substrate concentrations, including those within the ranges claimed by the '515 Patent, was known in the art well before the application which lead to the '515 Patent was filed.

8. The invention disclosed in the '515 Patent was therefore obvious as a matter of law in light of the existing prior art.

9. Upon information and belief, during prosecution of the '515 Patent the patentee failed to disclose all of the relevant prior art known to it and thereby failed to satisfy its duty of disclosure to the United States Patent and Trademark Office. Additionally, by manipulation of various measurements and units, the patentee sought to mislead the Patent and Trademark Office regarding the relationship between the claimed invention and the prior art. The '515 Patent is unenforceable as a result of this failure to disclose and/or inequitable conduct during the prosecution of the patent.

10. The specification for the '515 Patent provides specific guidelines for mixing a cardioplegic solution alleged to embody the claimed invention. However, these specified formulas fail to enable the production of cardioplegic solutions within the ranges claimed.

11. The plaintiff has consistently sold cardioplegic solutions which do not fall within the ranges claimed in the '515 Patent. Upon information and belief, the plaintiff has a practice of

marking its amino acid enriched cardioplegic solution product with the '515 Patent number, whether or not the particular product sold falls within the ranges claimed in the patent.

12. Upon information and belief, the plaintiff has adopted this practice with the intent of misleading its customers and the public into believing that the cardioplegic products that the plaintiff is providing cannot be purchased from any other source without infringing the '515 Patent.

13. In June, 2000, the plaintiff and defendant Advanced Cardiac Solutions, P.C. ("ACS") both submitted bids in response to a request for proposal to provide cardioplegic solutions to the University of New Orleans Medical Center. The request for proposal specified that the hospital sought a provider for amino acid enriched cardioplegic solutions, but did not specify the precise composition of the solution sought.

14. Upon information and belief, the plaintiff submitted with its bid a statement that any such amino acid enriched cardioplegic solutions would be covered by the '515 Patent, and could not be obtained from any source other than the plaintiff without infringing that patent. This statement was false, as a wide array of amino acid enriched cardioplegic solutions may be produced and sold which do not fall within the limited ranges claimed by the '515 Patent.

15. Upon information and belief, plaintiff has either willfully ignored the express limits of the patent's claims in taking the actions set forth above, or has adopted a construction of the patents claims which is patently unreasonable and foreclosed by the patentee's representations to the Patent and Trademark Office.

16. An actual controversy therefore exists between the parties hereto regarding the construction, validity, enforceability and infringement of the '515 Patent.

COUNT I
DECLARATORY JUDGMENT

17. Defendants incorporate herein and reassert by reference the allegations of paragraph 1-16 above as if set forth fully herein.

18. The '515 Patent is invalid and unenforceable.

19. Defendants have not infringed the '515 Patent.

20. Defendants are entitled to a definitive construction of the claims of the '515 Patent.

COUNT II
FALSE MARKING

21. Defendants incorporate herein and reassert by reference the allegations of paragraph 1-20 above as if set forth fully herein.

22. Upon information and belief, plaintiff has marked with the '515 Patent number products which do not fall within the claims that of that patent and are not covered by any other patent licensed to the plaintiff.

23. Upon information and belief, the plaintiff has done so with the intent to deceive the public.

24. Such false marking constitutes a violation of the United States Patent Laws, 35 U.S.C. § 292.

25. Defendants are entitled to recover statutory damages of \$500 for each such violation, subject to the right of the United States to receive half of the funds paid for its own use.

COUNT III
LANHAM ACT VIOLATION

26. Defendants incorporate herein and reassert by reference the allegations of paragraph 1-25 above as if set forth fully herein.

27. The plaintiff has falsely represented to its customers that certain amino acid enriched cardioplegic solutions fall within the claims of the '515 Patent, and/or that the sale of such solutions by anyone other than the plaintiff would constitute an infringement of the '515 Patent.

28. Such representations constitute misrepresentations regarding the nature, characteristics, and qualities of the cardioplegic products of plaintiff and defendant ACS made in the course of commercial advertising or promotion, in violation of the Lanham Act, 15 U.S.C. § 1125 (a)(1)(b).

29. Upon information and belief, such misrepresentations were made willfully and intentionally, and with the intent to deceive.

30. Defendant ACS has been injured thereby.

WHEREFORE, PREMISES CONSIDERED, the defendants pray for the following relief:

a) that this Court enter an Order declaring that the defendants have not directly or contributory infringed the '515 Patent, or induced the infringement of said patent;

b) that this Court enter an Order declaring that each and every claim of the '515 Patent is invalid, void and without force and effect;

c) that this Court enter an Order declaring that the '515 Patent is unenforceable;

d) that this Court enter an Order declaring the proper construction of the claims of the '515 Patent;

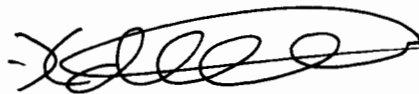
e) that this Court enter a Judgement against the plaintiff and in favor of the defendants for such actual and statutory damages as the defendants may prove at trial;

f) that this Court award the defendants their attorneys' fees, costs, and expenses in this action; and

g) that this Court grant such other and further relief as it may deem just and proper.

JURY DEMAND

THE DEFENDANTS DEMAND TRIAL BY JURY ON ALL ISSUES SO TRIABLE



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Attorneys for Defendants, Advanced Cardiac
Solutions, P.C. and Charles Wall

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CERTIFICATE OF SERVICE

I hereby certify that I have on this 2nd day of October, 2000, served a copy of the foregoing on counsel by mailing a copy of the same by United States Mail properly addressed and first class postage prepaid, to:

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A handwritten signature in black ink, appearing to read "J. G. [unclear]", is written over a horizontal line.

Of Counsel